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Use of Balloon Aortic Valvuloplasty to Size the Aortic Annulus Before Implantation of a Balloon-Expandable Transcatheter Heart Valve

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Objectives Our aim was to describe the use of balloon aortic valvuloplasty (BAV) to select proper transcatheter heart valve (THV) size.

Background Transesophageal echocardiogram (TEE) measurement alone of the aortic annulus may not be adequate to select a THV size. BAV can more accurately size the aortic annulus. We report our experience using this strategy in patients undergoing THV implantation.

Methods Twenty-seven patients underwent sizing of the aortic annulus by BAV and TEE. We implanted the minimal THV size that was greater than the annulus measured by BAV.

Results The annulus measured by TEE was 21.3 ± 1.6 mm and by BAV was 22.6 ± 1.8 mm ($p < 0.001$). The number of balloon inflations was 2.7 ± 0.7 (range 2 to 4), and the balloon sizes used were 22.0 ± 1.8 mm (range 20 to 25 mm). Fourteen patients (52%) required upsizing of the initial balloon suggested by TEE; rapid pacing duration was 8 ± 1.3 s (range 6 to 11 s). No change in aortic insufficiency or hemodynamic instability occurred with BAV. Fifteen patients (56%) received a 23-mm THV; 12 patients a 26-mm THV. No coronary occlusion, annular damage, or THV embolization occurred. Paravalvular leak was grade ≤1 in all patients. In 7 patients (26%), balloon sizing resulted in selection of a specific THV size that could not be done by TEE alone.

Conclusions BAV sizing of the aortic annulus is safe and is an important adjunct to TEE when selecting THV size. Implanting the minimal THV greater than the BAV annulus size resulted in no adverse events. These data suggest that use of BAV for THV selection may improve the safety and efficacy of THV implantation. (J Am Coll Cardiol Intv 2010;3:114–8) © 2010 by the American College of Cardiology Foundation

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Transcatheter heart valve (THV) implantation is used to treat a subset of high-risk or inoperable patients with aortic stenosis (1–6). There are 2 available THV sizes (Edwards Lifesciences, Irvine, California), and choosing the correct THV size based upon echocardiography measurements of the aortic annulus can be difficult or even inaccurate (2,5,6). We have previously described a technique to size the aortic annulus using balloon aortic valvuloplasty (BAV) catheters in patients undergoing surgical aortic valve replacement, and have since used this technique in our patients undergoing implantation with a balloon-expandable THV (7). This report describes the experience with BAV to size the aortic annulus, and the use of these findings to select the best THV size to minimize the risk of embolization, significant paravalvular leak (PVL), coronary obstruction, or damage to the aortic root.

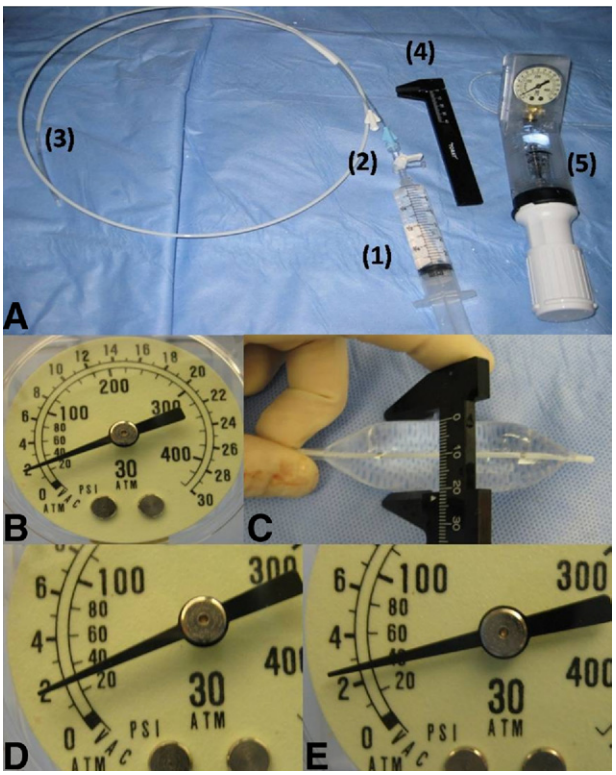

Figure 1. Preparation and Use of a BAV Catheter to Measure Aortic Annulus Size

(A) The equipment used for balloon aortic valvuloplasty (BAV) annulus sizing includes: (1) inflation syringe; (2) 4-way stop clock; (3) BAV catheter; (4) sterile caliper; and (5) indeflator pressure gauge. **(B)** The volume in the inflation syringe is adjusted so that complete emptying of the syringe results in a nominal pressure of 2 atms in the BAV catheter (measurement from indeflator pressure gauge shown). **(C)** At 2 atms, the balloon diameter is measured with sterile calipers. **(D)** The BAV catheter is inserted retrograde through the aortic valve and inflated with full volume. If the balloon diameter is smaller than the aortic annulus, the intraballoon pressure remains 2 atms. **(E)** If the balloon diameter is the same or larger than the aortic annulus, there is additional intraballoon pressure generated (>2 atms).

Methods

Twenty-seven patients undergoing transfemoral implantation of a THV for aortic stenosis were studied from January 2008 to April 2009. All patients were part of the PARTNER (Placement of AoRTic TraNscathetER Valve Trial, Edwards Lifesciences) trial to study the efficacy of a balloon-expandable THV (Edwards SAPIEN valve) in nonoperable or high-risk surgical candidates. The study was approved and performed in accordance with the regulations of the hospital institutional review board (Emory University Hospital, Atlanta, Georgia).

Echocardiographic measurements. Transesophageal echocardiograms (TEEs) were performed and interpreted by an experienced echocardiographer throughout the THV procedure. The aortic annulus (internal distance between the lowest insertion of the noncoronary and right coronary aortic cusp) was measured pre-implantation in the 3-chamber, long-axis view. When TEE was not possible, intraprocedure transthoracic echocardiogram was performed (parasternal long-axis view). Three measurements were made to confirm the annulus dimension. In cases of discordant measurement, the largest annular dimension was used. PVL was graded as 0 to 4 (none, mild, moderate, or severe) using color Doppler in a short-axis view of the THV immediately after implantation (8).

Abbreviations and Acronyms

AIBP = additional intraballoon pressure
BAV = balloon aortic valvuloplasty
PVL = paravalvular leak
TEE = transesophageal echocardiogram
THV = transcatheter heart valve

BAV. All patients had BAV (Z-MED balloons, NuMED, Inc., Hopkinton, New York) before THV implantation. In addition to dilating the native valve, BAV was used to size the aortic annulus. The protocol for balloon sizing the aortic annulus has been previously described and is summarized here and in Figure 1. The starting BAV catheter was selected so the diameter of the balloon was within 2 mm of the annulus measured by TEE; all balloon lengths were 4 cm. The BAV catheter was connected via 4-way stopclock to an indeflator device for pressure measurements and a 30 cc inflation syringe. The balloons were inflated on a sterile table, and the volume in the inflation syringe (saline/contrast mixture 7:1) was adjusted so that 2 atms of intraballoon pressure was generated at maximum inflation (Fig. 1B). Calipers were used to measure the balloon diameter at 2 atms (Fig. 1C). The balloon was then deflated, inserted retrograde through the aortic valve, and used for BAV during rapid, right ventricular pacing. At full inflation, the intraballoon pressure, measured on the inde-

flator gauge, was recorded. If the intraballoon pressure did not exceed 2 atms (Fig. 1D), there was no force exerted by the aortic annulus on the balloon, and, hence, the annulus was larger than the balloon. If the intraballoon pressure exceeded 2 atms (i.e., additional intraballoon pressure [AIBP] was present) (Fig. 1E), the annulus size had been reached or exceeded by the balloon. AIBP was calculated by subtracting the nominal inflation pressure (2 atms) from the intraballoon pressure generated during BAV. Two balloon inflations were done to verify pressure measurements. A schematic of BAV annulus sizing is shown in Figure 2.

THV selection and implantation. We selected the minimal THV size (23 or 26 mm diameter) that was greater than the balloon diameter that generated AIBP. Transfemoral implantation of the THV was performed by standard techniques previously described.

Statistical analysis. Comparison of aortic insufficiency (pre- vs. post-BAV) and annulus size (echocardiography vs. balloon sizing) were performed using a paired *t* test. Differences were considered statistically significant at a value of $p < 0.05$. All values were expressed as mean ± SD.

Results

Patient characteristics. Table 1 shows patient characteristics. All patients had tri-leaflet aortic valve degeneration. Four patients with nonrevascularized coronary artery disease were not amenable to stenting and/or bypass revascularization (1 nonoperable patient with chronic total occlusion of the right coronary artery with collaterals from the left coronary artery, 1 nonoperable patient with chronic total occlusion of the left anterior descending coronary artery [7] with bridging collaterals, 1 high-risk operable patient with proximally occluded left anterior descending coronary artery without collaterals and left internal mammary bypass to the diagonal branch, and 1 high-risk operable patient with occluded vein graft to a posterior descending artery, which was a poor target for regrafting).

Table 1. Baseline Patient Characteristics

	No. of Patients and Parameters (%)
Age, yrs (range)	83 (66–95)
Sex, male	13 (48)
Ejection fraction, % (range)	47 ± 14 (20–60)
Cardiac index, l/min/m^2 (range)	2.2 ± 0.7 (1.2–3.7)
Right ventricular dysfunction*	7 (26)
Porcelain aorta	5 (19)
Pulmonary hypertension†	11 (41)
Nonrevascularized CAD‡	4 (15)

*Moderate or severe right ventricular dysfunction by baseline transthoracic echocardiogram or transesophageal echocardiogram; †systolic pulmonary artery pressure ≥60 mm Hg; ‡see Results section.
CAD = coronary artery disease.

BAV procedure. Table 2 shows the details of the BAV procedure. To minimize the number of balloon inflations, we moved to larger balloon sizes if the initial balloon was too small (i.e., no AIBP). The average number of balloon inflations was <3, and the duration of rapid pacing was ≤10 s for 25 of 27 patients. BAV did not cause any change in aortic insufficiency (p = NS). Despite patients with depressed ejection fraction, low cardiac index, and porcelain aorta (Table 1), BAV with annulus sizing was

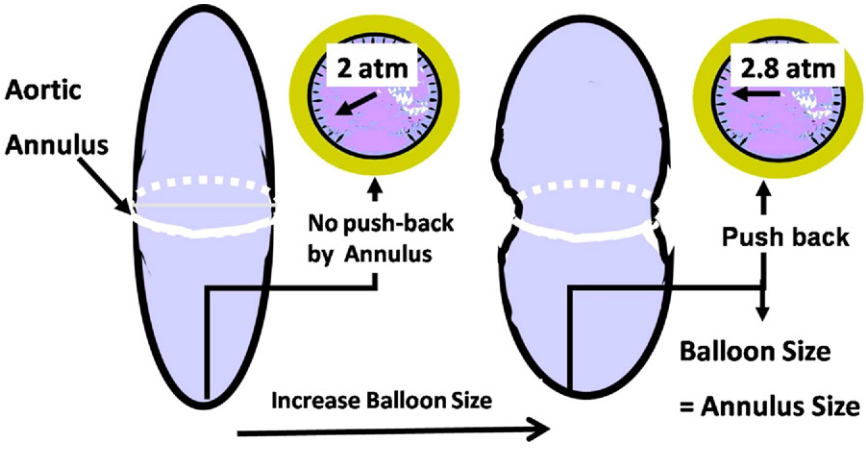

Figure 2. Schematic of Aortic Annulus Sizing by BAV Catheter

After preparation on a sterile table, the balloon aortic valvuloplasty (BAV) catheter is inflated across the aortic valve. If no additional intraballoon pressure is generated (i.e., 2 atms of intraballoon pressure or no push back by the annulus on balloon), the balloon is too small and the procedure should be repeated with a larger size. Once additional intraballoon pressure is generated (i.e., >2 atms intraballoon pressure or push-back by the annulus on balloon), the balloon annulus size has been reached.

Table 2. BAV Procedure Characteristics

	No. of Patients and Parameters (%)
Number of balloon inflations (range)	2.7 ± 0.7 (2–4)
Balloon sizes used, mm (range)	22.0 ± 1.8 (20–25)
Patients requiring 2 different balloons sizes	14 (52)
Duration of rapid pacing, s (range)	8 ± 1.3 (6–11)
Pre-BAV aortic insufficiency (range)	1.0 ± 0.5 (0–2)
Post-BAV aortic insufficiency (range)	1.1 ± 0.6 (0–2)
Hemodynamic instability post-BAV	0 (0)

BAV = balloon aortic valvuloplasty.

well tolerated without prolonged hypotension post-inflation or other complications.

THV selection and implantation. The implant selection data for each patient are shown in Table 3. On average, the annulus measured by BAV was >1 mm larger than that found on TEE ($p < 0.001$), with discrepancies up to 3.5 mm. Annulus measurement by BAV was most helpful in selecting THVs in 7 patients (26%) with TEE annulus size considered "borderline": patients with TEE annulus measurement of 21 mm (Patients #4, #13, #22, and #25), female patients with TEE annulus measurement of 22 mm (Patient #2), patients with TEE annulus measurement >24 mm (Patient #26), and patients unable to undergo TEE (Patient #27, male, 21-mm transthoracic echocardiogram annulus, 22-mm BAV annulus, implanted with a 23-mm THV). The THVs selected were 0.5- to 3.0-mm larger than the BAV annulus size (1- to 5-mm larger than TEE annulus size); a 23-mm THV was implanted in 15 of 27 (56%) patients. AIBP ranged from 0.2 to 2 atms (mode 0.5 atm). No patient experienced coronary occlusion, annular damage, or THV embolization. Using this sizing strategy, no significant PVL was seen after THV implantation (all patients grade ≤1 PVL).

Discussion

Our data support a strategy for selection of a THV that is based on balloon sizing. The advantages of this technique are: the balloon sizing is objective, the measurements can be made with existing devices, the data can be acquired safely during routine BAV, and the selection of THV is simple (use the smallest THV greater than the balloon annulus size). Using this strategy, we have performed 27 THV procedures without device complications from over- or undersizing. In approximately 1 of every 4 patients, balloon sizing resulted in selection of a specific THV size that could not be done by TEE alone.

Until now there have been 3 major strategies used to select a THV size: 1) the THV should be more than 2 mm larger than the TEE annulus; 2) a 23-mm THV should be implanted in female patients, and a 26-mm THV should be implanted in male patients; 3) the THV should be equal to or larger than the balloon that fills the annulus during BAV as visualized by echocardiography. There are limitations in all these methods. The TEE can be inaccurate because the annulus, which is measured in one view, is not a perfect circle (9,10). Small changes in angulation, rotation, and cursor placement during echocardiography can result in different measurements. Gender-specific implantation is based on the observation that an "average-sized" female requires a smaller THV and an "average-sized" male requires a larger THV. The criteria for "average-sized" patients remains vague, and THVs of either size have been implanted in men and women. Visual inspection during BAV is also subjective. Echocardiographic findings during balloon sizing of the aortic annulus are variable. In some patients, the balloon fills the annulus and the annulus does not stretch. In others, the balloon stretches the annulus. We

Table 3. Aortic Annulus by TEE and BAV Sizing With Corresponding THV Size Implanted

Patient #	Aortic Annulus by TEE (mm)	Aortic Annulus by BAV (mm)	AIBP (atm)	THV Size (mm)
1	20	20	1	23
2	22	22	2	23
3	20	20	1	23
4	21	23	2	26
5	19	20	1	23
6	20	21	2	23
7	23	24	0.5	26
8	20	20	0.5	23
9	20	20	0.5	23
10	24	24	0.5	26
11	20	22	0.5	23
12	20	22	1	23
13	21	22	0.75	23
14	23	24.5	0.5	26
15	24	24	0.5	26
16	23	23	0.5	26
17	23	24.5	0.5	26
18	22	25.5	0.2	26
19	23	25.5	0.3	26
20	20	22	0.8	23
21	20	22	0.5	23
22	21	20.5	0.5	23
23	23	24	0.5	26
24	24	25.5	1	26
25	21	22	1	23
26	24.5	25	0.5	26
27	21*	22	0.75	23
Mean ± SD	21.3 ± 1.6	22.6 ± 1.8	0.8 ± 0.5	24.2 ± 1.5

*Transthoracic echocardiogram measurement because patient was unable to have transesophageal echocardiogram (TEE).

BAV = balloon aortic valvuloplasty; IABP = intra-aortic balloon pressure; THV = transcatheter heart valve.

feel that these echo findings alone do not identify annular size. However, in either case, if the inflation generates AIBP, the correct annulus size has been identified regardless of the echo findings. Other less commonly used techniques for annulus sizing have been computed tomography (9,10), "waisting" of the balloon, and balloon inflation with simultaneous contrast injection to check the "stop flow" diameter (A. Cribier, personal communication, July 2009). These techniques may be of merit and await systematic evaluation.

Study limitations and future directions. The number of patients in this study was small, which reflects the THV experience of most U.S. centers. Further validation of this strategy will require more data from multiple centers. The balloons used in this study were of medium compliance and uniform length (4 cm). It is unknown if softer or less compliant balloons would improve or diminish the accuracy of these measurements. Currently we are studying longer length balloons (5 cm) using combination indeflator/inflation syringes with more detailed pressure gauges and strategies requiring fewer balloon inflations. Bicuspid valves were not studied as per the PARTNER (Placement of AoRTic TraNscathetER valve) study protocol. A modified sizing strategy could be studied in patients with bicuspid aortic valves in future THV protocols.

Conclusions

We have described a strategy to select THV size based upon aortic annulus measurement during BAV (minimal THV greater than the BAV annulus size). This strategy can be performed safely and is an important adjunct to TEE in patients with borderline echo measurements (26% of patients). As more THV sizes and newer devices become available, this method should have wider applicability. No adverse consequences of THV oversizing (annular disruption, vagally mediated hypotension secondary to annular stretch, coronary occlusion) or undersizing (THV embolization or PVL greater than grade 1) occurred using this method. These data suggest that this strategy of THV selection may improve the safety and efficacy of THV implantation.

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Key Words: percutaneous ■ transcatheter ■ aortic ■ valve ■ annulus ■ aortic stenosis ■ balloon aortic valvuloplasty.